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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,979	11/05/2007	Antoni Torrens Jover	283726US0PCT	9435
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
ODELL, DAVID K				
ART UNIT		PAPER NUMBER		
1625				
NOTIFICATION DATE		DELIVERY MODE		
12/16/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary**Application No.**

10/565,979

Applicant(s)

TORRENS JOVER ET AL.

Examiner

David K. O'Dell

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 31-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

1. This application is a 371 of PCT/EP04/08508 filed 07/29/2004, which claims priority to Espana P200301813 filed 07/30/2003

Claims 1-56 are pending.

2. *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-24, 29-30 drawn to compounds and compositions. If this group is elected, a further election of a single disclosed species of compound is also required. Further restriction based on the election may be made.

Group II, claims 25-28, drawn to methods of making the compounds of group I. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the species election will be required.

PLEASE NOTE: Claims 31-56 are non-statutory use claims and are withdrawn from consideration. Cancellation is recommended.

The inventions listed as Groups I-I do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because:

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, of if there is more than one invention, inclusion is permitted if they are so slinked to form a single general inventive concept.

Annex B **Part 1(b)**, indicates that “special technical features” means those technical features that as a whole define a contribution over the prior art.

Annex B **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

Annex B **Part 1(e)**, indicates that the permissible combinations of different categories of claims. **Part 1(e)I**, states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

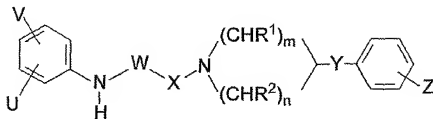
Annex B, **Part 1(f)**, indicates the “Markush practice” of alternatives in a single claim. **Part 1(f)I**, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f) iv**, indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f)v**, indicates that

“When dealing with alternatives, if it can be shown that at least *one* Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner”

In the instant case, at least one Markush alternative is not novel because prior art by WO03/ 0100159 (cited on the IDS and ISR) teaches compounds of claim 1, as the Formula I (page 3 where W is CO, X is CH₂ and Y is NR):

5 **Detailed description of the invention**

The present invention relates therefore first to new carboxylic acid amide derivatives of formula (I)



(I)

In the tables 5, & 6 shown below:

Table 5

Compounds of formula (I) prepared by procedure "B" described in Example 260
where X means -CH₂- group, both of -(CHR¹)_m- and -(CHR²)_n- are -CH₂-CH₂- groups Y, Z,
 5 **U and V are as given below:**

No.	V	U	Y	Z	MW _e	MW _f	k'
1	4-Amino-2-methylphenyl	4-Amino-2-methylphenyl	CH ₂	CH ₂	254.3	254.3	1.0

Art Unit: 1625

15.	4- HO-	H-	-CH ₂ -	4-CH ₃ -	338.451	339.5	2.33
16.	4- HO-	H-	CH ₃ -N<	4-Cl-	373.884	374.4	1.369
17.	4- Ac-NH-	H-	CH ₃ -N<	4-Cl-	414.937	415.4	1.785
18.	4- CH ₃ -SO ₂ -NH-	H-	CH ₃ -N<	4-Cl-	450.985	451.5	1.704
19.	4- CH ₃ -SO ₂ -NH-	H-	-CH ₂ -CH ₂ -	4-F-	433.542	434.3	2.504
20.	4- Ac-NH-	H-	-CH ₂ -CH ₂ -	4-F-	397.494	398.2	2.53
21.	4- HO-	H-	-CH ₂ -CH ₂ -	4-F-	356.441	357.2	2.325
22.	4- CH ₃ -SO ₂ -NH-	H-	CH ₃ -N<	4-CH ₃ -	430.567	431.3	1.332
23.	4- Ac-NH-	H-	CH ₃ -N<	4-CH ₃ -	394.519	395.3	1.433
24.	4- Ac-NH-	H-	CH ₃ -N<	4-Br-	459.388	460.2	1.864
25.	4- HO-	H-	CH ₃ -N<	4-Br-	418.335	419.2	1.461
26.	4- CH ₃ -SO ₂ -NH-	H-	CH ₃ -N<	4-Br-	495.436	496.3	1.793
27.	4- HO-	H-	CH ₃ -N<	4-CH ₃ -	353.466	354.3	1.027

Table 6

Compounds of formula (I) prepared by procedure "B" described in Example 260
where X means -CH₂- group, both of -(CHR)¹_m- and -(CHR)²_n- are -CH₂-CH₂- groups, U
and V form together a bivalent group and Y and Z are as given below:

Art Unit: 1625

76.	3-4 -N=CH-NH-	CH ₃ -N<	4-Cl-	397.91	398.5	1.296
77.	3-4 -O-CH ₂ -CO-NH-	CH ₃ -N<	4-Cl-	428.92	429.5	1.896
78.	3-4 -S-C(SH)=N-	CH ₃ -N<	4-Cl-	447.015	447.5	2.285
79.	3-4 -NH-C(CH ₃)=N-	CH ₃ -N<	4-Cl-	411.937	412.4	1.455
80.	3-4 -CH ₂ -CH ₂ -CO-NH-	CH ₃ -N<	4-Cl-	426.948	427.4	1.937

82.	3-4 -O-CO-NH-	CH ₃ -N<	4-Cl-	414.893	415.5	1.827
83.	3-4 -CH=N-NH-	CH ₃ -N<	4-Cl-	397.91	398.5	1.853
84.	3-4 -NH-N=CH-	CH ₃ -N<	4-Cl-	397.91	398.5	1.932
85.	3-4 -CH=CH-NH-	CH ₃ -N<	4-Cl-	396.922	397.5	1.862
86.	3-4 -CH=C(CH ₃)-NH-	CH ₃ -N<	4-Cl-	410.949	411.4	2.130
87.	3-4 -S-CO-NH-	CH ₃ -N<	4-Cl-	430.954	431.4	2.072

102.	3-4 -O-CO-NH-	CH ₃ -N<	4-CH ₃ -	394.475	395.2	1.467
103.	3-4 -NH-CO-O-	CH ₃ -N<	4-CH ₃ -	394.475	395.2	1.48
104.	3-4 -NH-CO-NH-	CH ₃ -N<	4-CH ₃ -	393.491	394.2	1.423

- 94 -

105.	3-4 -CH ₂ -CO-NH-	CH ₃ -N<	4-CH ₃ -	392.503	393.3	1.444
106.	3-4 -N=CH-NH-	CH ₃ -N<	4-CH ₃ -	377.492	378.2	0.966
107.	3-4 -O-CH ₂ -CO-NH-	CH ₃ -N<	4-CH ₃ -	408.502	409.3	1.544
108.	3-4 -CH=CH-NH-	CH ₃ -N<	4-CH ₃ -	376.504	377.2	1.453
109.	3-4 -S-C(SH)=N-	CH ₃ -N<	4-CH ₃ -	426.597	427.3	1.896
110.	3-4 -CH ₂ -CH ₂ -CO-NH-	CH ₃ -N<	4-CH ₃ -	406.53	407.3	1.574
111.	3-4 -NH-CS-NH-	CH ₃ -N<	4-CH ₃ -	409.552	410.3	1.455
112.	3-4 -S-CO-NH-	CH ₃ -N<	4-CH ₃ -	410.536	410.3	1.682
113.	3-4 -CH=C(CH ₃)-NH-	CH ₃ -N<	4-Br-	455.4	456.2	2.211
114.	3-4 -NH-C(CH ₃)=N-	CH ₃ -N<	4-Br-	456.388	457.2	1.522
115.	3-4 -CH ₂ -CH ₂ -CO-NH-	CH ₃ -N<	4-Br-	471.399	472.8	2.001
116.	3-4 -S-CO-NH-	CH ₃ -N<	4-Br-	475.405	476.2	2.159
117.	3-4 -CH=C(CH ₃)-NH-	CH ₃ -N<	4-CH ₃ -	390.531	391.3	1.708
118.	3-4 -CH=N-NH-	CH ₃ -N<	4-CH ₃ -	377.492	378.3	1.495
119.	3-4 -NH-N=CH-	CH ₃ -N<	4-CH ₃ -	377.492	378.3	1.572
120.	3-4 -O-CO-NH-	CH ₃ -N<	4-Br-	459.344	460.2	1.913

121.	3-4 -CH ₂ -CO-NH-	CH ₃ -N<	4-Br-	457.372	458.2	1.839
122.	3-4 -N=CH-NH-	CH ₃ -N<	4-Br-	442.361	443.2	1.39
123.	3-4 -O-CH ₂ -CO-NH-	CH ₃ -N<	4-Br-	473.371	474.2	1.986
124.	3-4 -NH-N=CH-	CH ₃ -N<	4-Br-	442.361	443.2	2.023
125.	3-4 -CH=N-NH-	CH ₃ -N<	4-Br-	442.361	443.2	1.949
126.	3-4 -CH=CH-NH-	CH ₃ -N<	4-Br-	441.373	442.2	1.953
127.	3-4 -S-C(SH)=N-	CH ₃ -N<	4-Br-	491.466	492.2	2.371
128.	3-4 -NH-CS-NH-	CH ₃ -N<	4-Br-	474.421	475.2	1.897
129.	3-4 -NH-C(CH ₃)=N-	CH ₃ -N<	4-CH ₃ -	391.519	392.3	1.151
130.	3-4 -NH-CO-O-	CH ₃ -N<	4-Br-	459.344	460.2	1.908

At least where B is methyl, the only difference is the change of H to Methyl (recited as alkyl radical in the instant claims). This non-patentable distinction makes it clear that applicants'

core is not a contribution over the prior art, thus the lack of a special technical feature is apparent.

Inventions I and II are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method making the compounds can be practiced by a materially different process, such as the construction of the piperidine ring.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

3. In addition to the selection of an elected group applicant is required to elect a species. Claims 1-22, 25-30 are generic to the following disclosed patentably distinct species: the compounds of claims 23-24. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571)272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

